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FOLEY AND LARDNER
SUITE 500
3000 K STREET NW
WASHINGTON, DC 20007

EXAMINER	
LU, FRANK WEI MIN	

ART UNIT	PAPER NUMBER
1634	

DATE MAILED: 10/06/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/763,233	HILLMAN ET AL.	
	Examiner	Art Unit	
	Frank W Lu	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *24 September 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-20* is/are pending in the application.

4a) Of the above claim(s) *9-11, 14, and 16-20* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-8,12,13 and 15* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restriction

1. Applicant's election with traverse of Group I, claims 1-8, 12, 13, and 15 and SEQ ID NO: 12 in the reply filed on September 1, 2004 is acknowledged. The traversal is on the ground(s) that: (1) "[G]roup I is drawn, in part, to polynucleotides which encode the polypeptides of claim 1. Likewise, although drawn to individual sequences, the claims of Group II are directed to polynucleotides which encode the polypeptides of claim 1. See, e.g., page 16, lines 6-10, of the Application, and Table 1, pages 53-56. Accordingly, Applicants respectfully request claims 9-11, of Group II, be rejoined with claims 1-8, 12, 13 and 15, of Group I, so that the claims may be examined together. Specifically and in view of the election of the polypeptide depicted in SEQ ID NO:12, Applicants request rejoinder of claims 9-11, as drawn to polynucleotides of SEQ ID NO:37, with the elected claims drawn to polynucleotides which encode the polypeptides of SEQ ID NO:12"; (2) "[T]he Polynucleotides Of Group I And The Polynucleotides Of Group II Exhibit A Common Special Technical Feature"; (3) "the search and examination of at least Groups I and II is not unduly burdensome" since "the polynucleotides of Group II are merely a species of the genus of polynucleotides of Group I"; and (4) "[I]n particular, as Applicants have elected Group I, as drawn to the polypeptide of SEQ ID NO:12, it is respectfully requested that claims 9-11 of Group II, as drawn to the polynucleotides of SEQ ID NO:37, be rejoined with claims 1-8, 12-13 and 15 of Group I".

The arguments have been carefully considered but they are not persuasive toward the withdrawal of the restriction of Groups I and II so that Groups I and II will be examined together. First, although selected polypeptide consisting of SEQ ID NO: 12 is encoded by a

polynucleotide consisting of SEQ ID NO: 37, claim 9 in Group II is not only limited to SEQ ID NO: 37. Second, according to previous restriction, the examiner stated that "[G]roups I and II do not relate to a single general inventive concept under PCT Rule 13.1 because the technical feature linking Groups I and II is not special. For example, an isolated and purified polynucleotide of Group II (ie., a fragment of SEQ ID No: 26) is not a contribution over the prior art wherein SEQ ID NO: 2 of US Patent No. 5,525,487 comprising poly(A) tail reads claim 9". Although applicant argues SEQ ID NO: 37 and does not argue SEQ ID NO:26, the examiner notes that SEQ ID No: 37 has a poly (A) tail and is not a contribution over the prior art wherein SEQ ID NO: 2 of US Patent No. 5,525,487 comprising poly(A) tail also reads a fragment of SEQ ID NO: 37 in claim 9. Thus, "[T]he Polynucleotides Of Group I And The Polynucleotides Of Group II Exhibit A Common Special Technical Feature" argued by applicant is incorrect. Third, as shown in previous office action, a search burden is not the reason for the restriction and the restriction is based on that the technical feature linking Groups I and II is not special. Therefore, the requirement is still deemed proper and is therefore made FINAL. Claims 1-8, 12, 13, and 15 and SEQ ID NO: 12 will be examined.

Priority

2. Since applicant claims priority for US provisional applications 60/097,550 and 60/115,639 in Oath/Declaration, according to 37 CFR 1.78(a)(2) and (a)(5), an application in which the benefits of an earlier application are desired must contain a specific reference to the prior application(s) in the first sentence of the specification or in an application data sheet,

applicant may consider to add the US provisional applications 60/097,550 and 60/115,639 in the first sentence of the specification.

Specification

3. This application does not contain an abstract of the disclosure as required by 37 CFR 1.72(b). A cover of WO 00/11171 can not considered as an abstract. An abstract on a separate sheet is required.

Claim Objections

4. Claim 1 is objected to because of the following informality: SEQ ID NOs: 1-11 and 13-25 must be deleted since applicant only elect SEQ ID NO: 12.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 1-8, 12, 13, and 15 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicant is referred to the interim guidelines on written description published on December 21, 1999 in the Federal Register at Volume 64, Number 244, pp.71427-71440.

Vas-Cath Inc. v. Mahurkar, 19USPQ2d 1111 (Fed. Cir. 1991), clearly states that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention is, for purposes of the 'written description' inquiry, whatever is now claimed." *Vas-Cath Inc. v. Mahurkar*, 19USPQ2d at 1117. The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed". *Vas-Cath Inc. v. Mahurkar*, 19USPQ2d at 1116.

The specification (Tables 1 and 2) provides adequate written description for a purified polypeptide consisting of an amino acid sequences of SEQ ID NO: 12 and its corresponding cDNA sequence (SEQ ID NO: 37) wherein SEQ ID NO: 12 is a cysteinyl-tRNA synthetase. However, the specification fails to adequately describe: (1) any kind of purified fragment from a substantially purified polypeptide comprising an amino acid sequence consisting of SEQ ID NO: 12 as recited in claim 1; (2) any kind of substantially purified variant having at least 90% amino acid sequence identity to SEQ ID NO: 12 and its fragments thereof as recited in claim 2; (3) any kind of isolated and purified polynucleotide encoding the polypeptide of SEQ ID NO: 12 and its fragments thereof as recited in claim 3; (4) any kind of isolated and purified polynucleotide variant having at least 70% polynucleotide sequence identity to the polynucleotide encoding the polypeptide of SEQ ID NO: 12 and its fragments thereof as recited in claim 4; (5) any kind of isolated and purified polynucleotide which hybridizes under stringent conditions to the

polynucleotide encoding the polypeptide of SEQ ID NO: 12 and its fragments thereof as recited in claim 5; (6) any kind of isolated and purified polynucleotide having a sequence which is complementary to the polynucleotide encoding the polypeptide of SEQ ID NO: 12 and its fragments thereof as recited in claim 6-8; (7) an expression vector comprising at least a fragment of the polynucleotide encoding the polypeptide of SEQ ID NO: 12 and its fragments thereof and a host cell comprising an expression vector comprising at least a fragment of the polynucleotide encoding the polypeptide of SEQ ID NO: 12 and its fragments thereof as recited in claims 12 and 13; and (8) a pharmaceutical composition comprising any kind of purified fragment from a substantially purified polypeptide comprising an amino acid sequence consisting of SEQ ID NO: 12 in conjunction with a suitable pharmaceutical carrier as recited in claim 15. The claimed inventions as a whole are not adequately described if the claims require essential or critical elements which are not adequately described in the specification and which are not conventional in the art as of Applicants effective filing date. Possession may be shown by actual reduction to practice, clear depiction of the invention in a detailed drawing, or by describing the invention with sufficient relevant identifying characteristics (as it relates to the claimed inventions as a whole) such that a person skilled in the art would recognize that the inventor had possession of the claimed invention. *Pfaff v. Wells Electronics, Inc.*, 48 USPQ2d 1641, 1646 (1998).

In this instant case, a substantially purified polypeptide recited in claim 1 is read as any kind of purified fragment from a substantially purified polypeptide comprising an amino acid sequence consisting of SEQ ID NO: 12. A substantially purified variant recited in claim 2 is read as any kind of substantially purified variant having at least 90% amino acid sequence identity to SEQ ID NO: 12 and its fragments thereof. An isolated and purified polynucleotide recited in

claim 3 is read as any kind of isolated and purified polynucleotide encoding the polypeptide of SEQ ID NO: 12 and its fragments thereof and these polynucleotides include any kind of fragments of SEQ ID NO: 12. An isolated and purified polynucleotide variant recited in claim 4 is read as any kind of isolated and purified polynucleotide variant having at least 70% polynucleotide sequence identity to the polynucleotide encoding the polypeptide of SEQ ID NO: 12 and its fragments thereof. An isolated and purified polynucleotide recited in claim 5 is read as any kind of isolated and purified polynucleotide which hybridizes under stringent conditions to the polynucleotide encoding the polypeptide of SEQ ID NO: 12 and its fragments thereof wherein the stringent conditions refers to conditions which permit hybridization between polynucleotides and the claimed polynucleotides (see the specification, page 14, lines 22-27). An isolated and purified polynucleotide recited in claim 6-8 is read as any kind of isolated and purified polynucleotide having a sequence which is complementary to the polynucleotide encoding the polypeptide of SEQ ID NO: 12 and its fragments thereof. An expression vector recited in claim 12 is read as an expression vector comprising at least a fragment of the polynucleotide encoding the polypeptide of SEQ ID NO: 12 and its fragments thereof. A host cell recited in claim 13 is read as a host cell comprising an expression vector comprising at least a fragment of the polynucleotide encoding the polypeptide of SEQ ID NO: 12 and its fragments thereof. A pharmaceutical composition recited in claim 15 is read as a pharmaceutical composition comprising any kind of purified fragment from a substantially purified polypeptide comprising an amino acid sequence consisting of SEQ ID NO: 12 in conjunction with a suitable pharmaceutical carrier. Although the specification adequately describes a purified polypeptide consisting of an amino acid sequences of SEQ ID NO: 12 and its corresponding cDNA

sequence (SEQ ID NO: 37) wherein SEQ ID NO: 12 is a cysteinyl-tRNA synthetase, claims 1-8, 12, 13, and 15 encompass numerous unknown fragments of SEQ ID No: 12 with different lengths and variants of SEQ ID No: 12 and its fragments thereof having at least 90% amino acid sequences identity to amino acid sequences of SEQ ID No: 12 and its fragments thereof, numerous unknown and unidentified polynucleotides encoding fragments of SEQ ID No: 12, complements of numerous unknown and unidentified polynucleotides encoding fragments of SEQ ID No: 12, and polynucleotide variants having at least 70% polynucleotide sequence identity to a polynucleotide encoding the polypeptide of SEQ ID NO: 12 and its fragments thereof that miss from the disclosure. It is unclear whether these numerous unknown fragments of SEQ ID No: 12 with different lengths and these unknown and unidentified polynucleotides or their variants can still function as a cysteinyl-tRNA synthetase as SEQ ID NO: 12 does and still can encode a functional cysteinyl-tRNA synthetase as SEQ ID NO: 37 does. Therefore, the general knowledge and level of skill in the art do not supplement the omitted description because specific, not general, guidance is what is needed.

With limited disclosure provided by the specification, the skilled artisan cannot envision all possible fragments of SEQ ID NO: 12 and variant polynucleotides which would be homologous to or hybridize to or fragments from polynucleotide encoding the polypeptide of SEQ ID NO: 12, and therefore conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method used. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method of identifying it. See *Fiers v. Revel*, 25 USPQ2d 1601, 1606 (Fed. Cir. 1993) and *Amgen Inc. v. Chugai Pharmaceutical Co.* Ltd., 18 USPQ2d 1016 (Fed. Cir. 1991).

One cannot describe what one has not conceived. See *Fiddes v. Baird*, 30 USPQ2d 1481, 1483. In *Fiddes,* claims directed to mammalian FGF's were found to be unpatentable due to lack of written description for that broad class. The specification provided only the bovine sequence.

Therefore, only a purified polypeptide consisting of SEQ ID No: 12 and its corresponding cDNA consisting of SEQ ID NO: 37 meet the written description provision of 35 U.S.C. §112, first paragraph. Applicant is reminded that *Vas-Cath* makes clear that the written description provision of 35 U.S.C. §112 is severable from its enablement provision (see page 1115).

7. Claims 1, 2, and 15 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

In *In re Wands*, 858 F.2d 731,737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988) the court considered the issue of enablement in molecular biology. The Court summarized eight factors to be considered in a determination of "undue experimentation". These factors include: (a) the quantity of experimentation necessary; (b) the amount of direction or guidance presented; (c) the presence or absence of working examples; (d) the nature of the invention; (e) the state of the prior art; (f) the relative skill of those in the art; (g) the predictability of the art; and (h) the breadth of the claims. The Court also stated that although the level of skill in molecular biology is high, results of experiments in molecular biology are unpredictable.

To begin, here is no direction or guidance in the specification to show that: (1) a substantially purified polypeptide comprising an amino acid sequence consisting of SEQ ID

NO:12 and fragments thereof and a substantially purified variant having at least 90% amino acid sequence identity to the amino acid sequence of a substantially purified polypeptide comprising an amino acid sequence consisting of SEQ ID NO:12 and fragments thereof can function as a cysteinyl-tRNA synthetase; and (2) a composition comprising a substantially purified polypeptide comprising an amino acid sequence consisting of SEQ ID NO:12 and fragments thereof in conjunction with a suitable pharmaceutical carrier can be used as a pharmaceutical composition. While the relative skill in the art is very high (the Ph.D. degree with laboratory experience), there is no predictability whether a substantially purified polypeptide comprising an amino acid sequence consisting of SEQ ID NO:12 and fragments thereof and a substantially purified variant having at least 90% amino acid sequence identity to the amino acid sequence of a substantially purified polypeptide comprising an amino acid sequence consisting of SEQ ID NO:12 and fragments thereof can function as a cysteinyl-tRNA synthetase and a composition comprising a substantially purified polypeptide comprising an amino acid sequence consisting of SEQ ID NO:12 and fragments thereof in conjunction with a suitable pharmaceutical carrier can be used as a pharmaceutical composition.

The invention is directed to a substantially purified polypeptide comprising an amino acid sequence consisting of SEQ ID NO:12 and fragments thereof and a substantially purified variant having at least 90% amino acid sequence identity to the amino acid sequence of a substantially purified polypeptide comprising an amino acid sequence consisting of SEQ ID NO:12 and fragments thereof, and a composition comprising a substantially purified polypeptide comprising an amino acid sequence consisting of SEQ ID NO:12 and fragments thereof in conjunction with a suitable pharmaceutical carrier. First, according to the specification, "substantially purified"

refers to amino acid sequences at least about 60% free from other components with which they are naturally associated (see the specification, page 14, lines 28-31). Since a substantially purified polypeptides recited in claims 1 and 2 only are 60% pure, it is unclear whether these purified polypeptides can function as a cysteinyl-tRNA synthetase as 100% pure cysteinyl-tRNA synthetase does since, from the specification, it is unclear whether other components that are naturally associated with cysteinyl-tRNA synthetase can inhibit the functions of cysteinyl-tRNA synthetase when cysteinyl-tRNA synthetase is associated with other components. Second, a pharmaceutical composition recited in claim 15 is read as a composition used for the purpose of treating a disease. However, the specification does not show that a composition comprising a substantially purified polypeptide comprising an amino acid sequence consisting of SEQ ID NO:12 and fragments thereof in conjunction with a suitable pharmaceutical carrier can be used to treat a disease. Therefore, there will be a lot of unpredictable factors when the skilled artisan uses the claimed substantially purified polypeptides and pharmaceutical composition and the skilled artisan will have no way to predict the experimental results. Such efforts constitute undue experimentation. The undue experimentation at least includes to test: (1) whether a substantially purified polypeptide comprising an amino acid sequence consisting of SEQ ID NO:12 and fragments thereof and a substantially purified variant having at least 90% amino acid sequence identity to the amino acid sequence of a substantially purified polypeptide comprising an amino acid sequence consisting of SEQ ID NO:12 and fragments thereof can function as a cysteinyl-tRNA synthetase; and (2) whether a composition comprising a substantially purified polypeptide comprising an amino acid sequence consisting of SEQ ID NO:12 and fragments thereof in

conjunction with a suitable pharmaceutical carrier can be used as a pharmaceutical composition to treat a disease.

8. Claims 7 and 8 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for performing the method recited in claims 7 and 8 using an isolated and purified polynucleotide recited in claim 6 in a certain length range, does not reasonably provide enablement for performing the method recited in claims 7 and 8 using the polynucleotide recited in claim 6 in any length. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

In *In re Wands*, 858 F.2d 731,737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988) the court considered the issue of enablement in molecular biology. The Court summarized eight factors to be considered in a determination of "undue experimentation". These factors include: (a) the quantity of experimentation necessary; (b) the amount of direction or guidance presented; (c) the presence or absence of working examples; (d) the nature of the invention; (e) the state of the prior art; (f) the relative skill of those in the art; (g) the predictability of the art; and (h) the breadth of the claims. The Court also stated that although the level of skill in molecular biology is high, results of experiments in molecular biology are unpredictable.

To begin, here is no direction or guidance in the specification to show that the method recited in claims 7 and 8 can be performed using the polynucleotide recited in claim 6 in any length. While the relative skill in the art is very high (the Ph.D. degree with laboratory

experience), there is no predictability whether the method recited in claims 7 and 8 can be performed using the polynucleotide recited in claim 6 in any length.

The invention is directed to a method for detecting a polynucleotide by hybridizing the polynucleotide encoding SEQ ID NO: 12 and fragment thereof with any length. It is well known that, as the length of an oligonucleotide increases, the chance that it will find an exact match in the genome of interest decreases. A longer oligonucleotide increases the specificity of hybridization (Sambrook et al., Molecular Cloning: A Laboratory Manual, page 11.7, 1989). On the other hand, the shorter the oligonucleotide is, the more non-specific hybridization is. It is clear that, if a skilled artisan choose a 8 bp sequences and search nucleotide databases, it would be expected to find the same or highly homologous (80-90%) 8 bp sequences in numerous other unrelated genes. Since claims 7 and 8 do not define the length of polynucleotide recited in claim 6, it is unclear how a skilled artisan can distinguish a specific hybridization complex formed by the polynucleotide recited in claim 6 and a nucleic acid from hybridization complexes formed by the polynucleotide recited in claim 6 and other nucleic acids that nonspecifically hybridize to the polynucleotide recited in claim 6. Therefore, there will be a lot of unpredictable factors when the skilled artisan uses the claimed the methods and the skilled artisan will have no way to predict the experimental results. Such efforts constitute undue experimentation. The undue experimentation at least includes to test whether the method recited in claims 7 and 8 can be performed using the polynucleotide recited in claim 6 with any length.

Claim Rejections - 35 USC § 102

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

10. Claims 5 and 6 are rejected under 35 U.S.C. 102(b) as being anticipated by New England Biolabs 96/97 Catalog (page 114).

Regarding claims 5 and 6, since a polynucleotide consisting of SEQ ID NO: 37 encodes a polypeptide consisting of SEQ ID NO: 12 (see applicant's remarks, page 3), one of the polynucleotide recited in claim 3 must be SEQ ID NO: 37. Since New England Biolabs 96/97 Catalog teaches a linker of Sma I with nucleotide sequence of (5'-CCCCGGGG-3', #1033) that is capable of hybridizing to nucleotides 398-405 of SEQ ID NO:37 (5'-AGGGCCCG-3'), and the stringent conditions refers to conditions which permit hybridization between polynucleotides and the claimed polynucleotides (see the specification, page 14, lines 22-27), New England Biolabs 96/97 Catalog discloses that an isolated and purified polynucleotide (ie., 5'-CCCCGGGG-3', #1033) which hybridizes under stringent conditions to the polynucleotide of claim 3 (ie., SEQ ID NO: 37) and an isolated and purified polynucleotide (ie., 5'-CCCCGGGG-3', #1033) having a sequence which is complementary to the polynucleotide of claim 3 (ie., SEQ ID NO: 37) as recited in claims 5 and 6.

Therefore, New England Biolabs 96/97 Catalog teaches all limitations recited in claims 5 and 6.

11. Claims 5-7 are rejected under 35 U.S.C. 102(b) as being anticipated by Sibson (US Patent No. 5,728,524, 102 (e) date: January 13, 1995).

Regarding claims 5 and 6, since a polynucleotide consisting of SEQ ID NO: 37 encodes a polypeptide consisting of SEQ ID NO: 12 (see applicant's remarks, page 3), one of the polynucleotide recited in claim 3 must be SEQ ID NO: 37. Since SEQ ID NO: 37 contains a poly(A) tail (see Sequencing listing in the specification) and the stringent conditions refers to conditions which permit hybridization between polynucleotides and the claimed polynucleotides (see the specification, page 14, lines 22-27), and Sibson teaches oligodT (see column 13, lines 16-57) that is capable of hybridizing to a poly(A) tail, Sibson discloses that an isolated and purified polynucleotide (ie., oligodT) which hybridizes under stringent conditions to the polynucleotide of claim 3 (ie., SEQ ID NO: 37) and an isolated and purified polynucleotide (ie., oligodT) having a sequence which is complementary to the polynucleotide of claim 3 (ie., SEQ ID NO: 37) as recited in claims 5 and 6.

Regarding claim 7, Sibson teaches that polyA$^+$ (mRNA) is isolated from 200 to 400 μg of the total RNA by binding it to magnetic oligodT coated beads (Dynal). Solution containing unbound material is removed from the beads, which are washed, and then mRNA eluted directly for use. mRNA isolation is performed in accordance with the manufacturers instructions. Yields of RNA from the beads are between 1 and 3% of the total RNA. 2 to 4 μg of the eluted RNA is used for cDNA synthesis (see column 13, lines 16-57). Since Sibson teaches that polyA$^+$

(mRNA) is isolated from 200 to 400 μg of the total RNA by binding it to magnetic oligodT coated beads (see column 13, lines 16-57), Sibson discloses hybridizing the polynucleotide of claim 6 (ie., oligodT) to at least one nucleic acid in a sample (ie., polyA$^+$ (mRNA)), thereby forming a hybridization complex as recited in step a) of claim 7. Since Sibson teaches that, after unbound material is removed from the beads by washing, mRNA eluted directly from the beads (see column 13, lines 16-57) and the presence of mRNA in the eluted buffer indicates the presence of the hybridization complex formed by polyA$^+$ (mRNA) and oligodT. Thus Sibson discloses indirectly detecting the hybridization complex by detecting eluted mRNA wherein the presence of the hybridization complex correlates with the presence of the polynucleotide in the sample as recited in claim 7.

Therefore, Sibson teaches all limitations recited in claims 5-7.

Conclusion

12. No claim is allowed.

13. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993)(See 37 CAR § 1.6(d)). The CM Fax Center number is either (703) 872-9606.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Frank Lu, Ph.D., whose telephone number is (571)272-0746. The examiner can normally be reached on Monday-Friday from 9 A.M. to 5 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion, can be reached on (571)272-0782.

Any inquiry of a general nature or relating to the status of this application should be directed to the Chemical Matrix receptionist whose telephone number is (703) 308-0196.

Frank Lu
PSA
September 28, 2004

FRANK LU
PATENT EXAMINER